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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,060	02/08/2005	Zhiming Suo	US 1421/05 (VA)	4405

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EXAMINER

WANG, CHANG YU

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/524,060

Applicant(s)

SUO ET AL.

Examiner

Chang-Yu Wang

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-13 in part, drawn to the first technical feature GRK-2 and first method of use for detecting Alzheimer's pathogenesis caused by GRK abnormal distribution.

Group II, claim(s) 1-13 in part, drawn to the second technical feature GRK-5 and the first method of use for detecting Alzheimer's pathogenesis caused by GRK abnormal distribution.

Group III, claim(s) 14-18, drawn to the third technical feature  $\beta$ -amyloid and the first method of use for detecting Alzheimer's pathogenesis caused by accumulation of  $\beta$ -amyloid.

Group IV, claim(s) 19-23, drawn to the fourth technical feature, a peptide, and the first method of use for inhibiting GRK-GPCR interaction.

Group V, claim(s) 24-28, drawn to the fourth technical feature a peptide and the second method of use for inhibiting desensitization of GPCR.

Group VI, claim(s) 29-31, drawn to the method of preventing or suppressing Alzheimer's disease progression.

Group VII, claim(s) 32, drawn to the fifth technical feature soluble  $\beta$ -amyloid antagonist and the first method of use for correcting soluble  $\beta$ -amyloid induced by GRK dysfunction.

Group VIII, claim(s) 33, drawn to the sixth special technical feature vaccine containing  $\beta$ -amyloid analog.

The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

2. The molecules used in Groups II-VIII are different peptides, which are not required by the Group I. Therefore, Groups II-VIII have different special technical features than Group I, since they define separate contributions to the art.

3. In addition, the pathogenesis of Alzheimer's disease has not had any evident conclusion although the amyloid plaques and neurofibrillary tangles are the major observations in the brain in patients with Alzheimer's disease. In this instant case, the abnormal distribution of GRK or  $\beta$ -amyloid accumulation could be just one of the possible mechanisms contributing to the cause of Alzheimer's disease. The mechanism for abnormal distribution of GRK in the cell could be due to GRK protein processing, trafficking, phosphorylation or regulation by other molecules. It requires tremendous efforts to understand the whole scope of cell biological mechanisms, which have not been fully established. In addition, GPCRs, the substrates for GRK, consist of a huge

group of different functional families of receptors, involved in endocrinological, immunological, cardiovascular, developmental, and neurological disorders etc. They might be involved in the cause of Alzheimers' disease solely and independent from the accumulation of  $\beta$ -amyloid or the distribution of GRK.

4. Therefore, the above Inventions do not share a common technical feature as they comprise distinct steps and utilize different products, which demonstrates that each method has a different mode of operation. Each invention uses structurally and functionally divergent materials. The methodology and materials necessary for detecting Alzheimer's disease pathogenesis significantly differ from those of prevention or suppression of Alzheimer's disease progression or those of inhibiting desensitization of GPCR. The effects and outcomes of each invention also are very divergent. Accordingly, Groups I-VIII are not so linked by the same or a corresponding special technical feature within meaning of PCT Rule 13.1 so as to form a single general inventive concept.

#### ***Species Election***

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

I. The species for the disruption in normal distribution of GRK are as follows:

- A. A prodromal stage of Alzheimer's disease
- B. The subcellular distribution of GRK
- C. The reduction in membrane associated GRK
- D. The increase in cytosolic GRK

II. The species for peptides are as follows:

- A.  $\beta$ -amyloid
- B. Soluble  $\beta$ -amyloid

6. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

7. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The claims are deemed to correspond to the species listed above in the following manner:

If Groups I or II is elected, Applicant is required to elect a specific disruption of distribution of GRK, wherein specific disruption of distribution of GRK selected from the group recited in claims 1-7. In addition, Applicant is required to select a species for peptides from the group recited in claims 7-9.

The following claim(s) are generic: claim 1 and 7.

9. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

10. The technical features of these species are distinct because each specific species differs with respect to its potential molecular mechanisms. There are several possible mechanisms to disrupt the cellular distribution of GRK. The increase or decrease in membrane associated GRK does not accordingly reflect to the subcellular distribution of GRK. The change of membrane associated GRK could be due to the change of the gene expression of GRK or the regulation of GRK protein processing/trafficking. In addition, the change of subcellular distribution of GRK does not necessarily change the level of membrane associated GRK. In addition, the biochemical properties of soluble  $\beta$ -amyloid are quite different from regular  $\beta$ -amyloid.

11. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143). In order to be fully responsive, Applicant is required to elect a single group from designated groups I-VIII and a single species of disruption of GRK as well as a single species of peptides as set forth above to which the claims will be restricted, even though the requirement is traversed. The subject matter for examination will be restricted to the extent of the subject matter of the elected groups and species.

12. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

13. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, PhD. whose telephone number is 571-272-4521. The examiner can normally be reached on Monday through Friday 8:00am to 5:00pm.



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph.D. can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW  
August 24, 2005

  
SHARON TURNER, PH.D.  
PRIMARY EXAMINER  
8/29/05